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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/100,088	06/19/98	BROWN	P 1606.0020004

EXAMINER	

ART UNIT	PAPER NUMBER
2123	11

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DATE MAILED: 01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/100,088	Brown
Examiner	**Group Art Unit**
Hugh Jones	2123

☒ Responsive to communication(s) filed on *Dec 19, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 2, and 4-17* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, and 4-17* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Information Disclosure Statement

1. Applicant has requested that Examiner review six co-pending applications including all art contained therein. As Applicant can appreciate, this places an extreme burden on the Examiner (*as well as the other six Examiners)* because the seven Examiners must review each application *every time art is added* to *each* application, and *each time* the claims in each application are *amended.* In the interest of compact prosecution, the Examiner would be appreciative if the Applicant would kindly supply copies of the indicated applications. The Examiner will consider any additional prior art provided in a proper IDS form 1449. Finally, Examiner requests a claim matrix of all applications which Representative considers related so that Examiner can review all applications for possible double patenting.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. **Claims 1-2 and 4-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.** The limitations of claims 1-2 and 4-9 are directed to abstract ideas. There is no pre-processing or post-processing of real world data. The limitations of claims 10-17 are directed to *media incorporating* algorithmic programs on a computer.

However, a claim directed at execution requires further consideration. The mere fact that a hardware element is recited in a claim does not necessarily limit the claim to a specific machine. *Cf.* In re *Iwahashi*, 888 F.2d 1370, 1374-75, 12 USPQ2d 1908, 1911-12 (Fed. Cir. 1989), *cited with approval in Alappat*, 33 F.3d at 1544 n.24, 31 USPQ2d at 1558 n.24. If a product claim encompasses *any* and every computer implementation of a process, when read in light of the specification, it should be examined on the basis of the underlying process. Such a claim is recognized as such because it will:

- define the physical characteristics of the computer component exclusively as functions or steps to be performed on or by a computer, and
- encompass *any and every* product in the stated class (e.g., computer, computer-readable memory) *configured in any manner* to perform that process.

Thus, even if the program were being executed, but there was no pre-processing or post-processing of real world data, i.e., *the underlying process was non-statutory*, the claims would not be statutory.

4. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The statement, "*contains information that can be used to determine an optimal design for a biopharmaceutical batch process manufacturing facility*" is not a specific utility because it does not inform a reader how to actually use the invention.

5. Claims 1-2 and 4-17 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for

the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. What does *optimal design* mean (last limitation of claim 1, for example)?

9. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: "... *contains information that* ***can be used to determine*** *an optimal design for a biopharmaceutical batch process manufacturing facility*". There is no limitation disclosing *how it can be used* or *actually using* it. Applicant is claiming a *simulation* of process scheduling for a specific industry.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-2 and 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over [Skeirik (*of record*) *or* Atherton (Applicant's IDS) *or* Iwasaki et al. (Applicant's IDS) *or* Litt et al. (Applicant's IDS) *or* Furukawa et al. (*of record*) *or* Carrette et al. (*of record*) *or* Leitch et al. *or* Ketcham et al. *or* Bernstein et al. *or* Ehrlich et al. *or* Arai et al. *or* Britt et al. (*Applicant's supplemental IDS*)] and further in view of the taking of [*Official Notice*] and [*Applicant's Own Admission*].

12. Skeirik discloses: a process control system with reconfigurable expert rules and control modules. From the abstract;

> "An integrated system for process control in which a process supervisor procedure (which is preferably the top-level procedure) is configured as a modular software structure, with modules that can be revised by a user at any time, without significantly interrupting the operation of the process supervisor. The modular software can define control parameters for many process control procedures, and can retrieve data from many sources (preferably including a historical database of process data, which can provide time-stamped data). The supervisor can also call on various expert subprocedures. Preferably the expert subprocedures can also be modified by an authorized user at any time, by calling up and editing a set of natural-language rule templates which correspond to the rules being executed by the expert subprocedure."

See also: fig. 1-2, 7-8, 15-18; col. 1-18 (details concerning the expert system and its use in process control).

13. Atherton discloses: real world modeling and process control. Col. 1 discloses the background; col. 2 discloses details concerning "due dates" and scheduling theory; col. 3 discloses simulation models of factories and their use in schedule generation; col. 4 discloses details concerning batch, sampling, and process control; col. 4 discloses the taking into account of equipment reliability and other details involved in process modeling; col. 10 discloses an algorithm for process modeling; cols. 11-16 disclose details concerning sequences, batching, scheduling rules.

14. Iwasaki et al. discloses: "Production system with order of processing determination". See: col. 2-3 (details concerning scheduling a processing line); col. 6 (use of sampling data).

15. Litt et al. disclose: "Expert system and method for batch production scheduling and planning." See: abstract; fig. 2-7; col. 1-2 (details concerning the use of rule-based expert systems in process scheduling, batch scheduling, delivery dates, production constraints).

16. Furukawa et al. disclose a production control system. See: abstract; fig. 3a (scheduling and its interaction with the production line), fig. 3c (lead time), fig. 4a (scheduling), fig. 4c (overview), fig. 5 (scheduling), fig. 20-23 (details about scheduling), fig. 31 (table), fig. 41 (tables, pointers, scheduling), fig. 60-63 (overview); see text corresponding to said figures.

17. Carrette et al. disclose: Method and apparatus for real-time control. See: abstract; fig. 1-2, 4-8, 13, 21-24 and corresponding text.

18. Leitch et al. disclose, "*A real-time knowledge based system for product quality control.*"

The abstract discloses:

> "An ICI plant in the north of England has two batch reactors producing a large number of products consisting of ethoxylates. It is controlled by a Foxborough Fox 1/A process sequence control computer. The task of the plant operators is to set the 'recipe' on the Fox 1/A to make products at the desired quality and to initiate and monitor the process sequence. When a batch has been produced they judge its quality and can take a sample for laboratory analysis. If they judge it necessary they may make an adjustment or take other remedial action. The paper concerns an expert system which makes recommendations to the operator when he makes his decisions. *To achieve this it must monitor and form judgements on the plant and raw materials affecting product quality; provide a prediction of product quality; estimate errors in instrumentation; and provide a justification for its recommendations.*

Index Terms:

> general-purpose detergents; chemical reactors; real-time knowledge based system; product quality control; ICI plant; batch reactors; ethoxylates; Foxborough Fox 1/A process sequence control computer; expert system; batch processing (industrial); chemical industry; chemical variables control; expert systems; process computer control; quality control."

See, also: sections entitled "Application", "The knowledge based system", and particularly, "The quality control system".

19. Ketcham et al. disclose a generic simulator for continuous flow manufacturing. They disclose quality control (abstract, col. 1, page 609); tooling layout (col. 2, page 610), product batching (col. 1, page 611), and a process simulation (section 5).

20. Bernstein et al. diclose a simulation-based decision support system for a speciality chemicals production plant that can be used in an off-line mode. Col. 1, page 1263 discloses that the simulation is carried out prior to any capital investment, and also discusses the database, used in the simulation. Section 2 discloses scheduling and operations issues. Section 3 discloses a

simulation execution module including simulation of batch processing and sequencing and a knowledge base.

21. Ehrlich et al. disclose AIM which is a manufacturing process modeller. Section 1.1 discloses that the simulation is carried out before physical implementation. Section 1.3.1 discloses the model. Section 1.3.2 discloses modelling of scheuling. Section 3 discloses the GUI interface and simulation of batch processing.

22. Arai et al. disclose an automatic analysis system. See the abstract. Col. 2, line 51 to col. 2, line 63 disclose:

> *"That is to say, according to the first aspect of the present invention, there is provided an automatic analysis system which comprises an analytical equipment and a host computer connected to the analytical equipment, said host computer comprising control means for giving identification numbers for identification to pieces of analysis information such as an analytical measurement test sample name, an analytical measurement test item name, an analytical measurement test method name, an analytical measurement tester name, an analytical measurement test requester, i.e., a customer name as well as lower limit values, errors, analysis accuracies and units of an analytical measurement test, respectively, further giving identification numbers to the pieces of analysis information, respectively, to relate the pieces of analysis information to each other, grouping a predetermined number of the pieces of analysis information to form pieces of group information, giving identification numbers to the pieces of group information, respectively, further grouping a predetermined number of the pieces of group information to form pieces of group information, and then giving identification numbers to the pieces of group information, respectively, and storage means for storing the pieces of analysis information and group information to which the identification numbers are given by the control* means.
>
> According to the second aspect of the present invention, there is provided an automatic analysis system which comprises an analytical equipment and a host computer connected to the analytical equipment, said host computer comprising control means having functions of giving first identification numbers to pieces of analysis information, respectively, to mutually identify the pieces of analysis information and to relate the pieces of analysis information to each other, grouping a predetermined number of the pieces of analysis information to form pieces of first group information, giving second identification numbers to the pieces of first group information, respectively, further grouping the pieces of first group information in accordance with a predetermined viewpoint to form

pieces of second group information, and then giving third identification numbers to the pieces of second group information, respectively, and storage means for storing the pieces of analysis information to which the first, second and third identification numbers are given by the control means.

Moreover, *in the present invention, the respective pieces of analysis information are grouped in accordance with a common attribute to form the first group information, and the respective pieces of analysis information are grouped in accordance with the property or purpose of the respective pieces of analysis information such as a chemical composition, an analytical measurement test method or an analytical result report preparation method to form the second group information. Furthermore, the identification numbers are given to the pieces of the first and second group information, and these pieces of the information are then stored, whereby the handling of the information can be preferably improved.*

In the present invention, the respective pieces of analysis information basically comprise measured data and relevant information other than the measured data, and to these pieces of analysis information, identification numbers are given. Then, they are stored in storage means. These pieces of analysis information are retrieved by the control means, read in a mutually related manner, processed and then edited, and the final results are output by output means such as a printer.

Furthermore, *in present invention, the respective pieces of analysis information necessary for an analytical measurement test such as a test item, a test sequence, a test method and test conditions are read from the storage means prior to the execution of the analytical measurement test, and these pieces of analysis information are output as an arrangement document, whereby artificial errors can be prevented and the analytical measurement test can be correctly and smoothly carried out*.

Moreover, in the middle stage of the analytical measurement test, the analysis progress state is read out from the storage means, whereby reference can be made and the control of the analytical measurement test can be accurately and quickly accomplished. In addition, the efficiency of the analytical measurement test can be improved."

23. Britt et al. disclose (abstract):

"*A software system simulates and optimizes a processing plant design. The software system includes a plurality of equipment models for simulating each piece of equipment in the processing plant design. A sequential modular simulation routine executes the equipment models in a first mode to define a first set of values of the operating parameters of the processing plant design. An optimization routine executes the equipment models in a second mode. The optimization routine utilizes the first set of values for the operating parameters from the sequential simulation routine and subsequently determines values of the operating parameters at which the processing plant design is optimized. The equipment models after execution by the sequential simulation routine and optimization routine store the first and second sets of values for the operating parameters in a common plant model file. Hence,*

the plant model file holds values computed during the sequential simulation routine as well as those computed during the optimization routine."

Col. 4, line 36 to col. 5, line 26 disclose:

"Applicants have discovered that the better software system for simulating and optimizing process plant designs is one which:

a) solves the initial plant model through sequential modular simulation. This generates an initial point. and

b) generates an equation oriented plant model which is initialized from the solution in a). This equation oriented model is then used for data reconciliation, parameter estimation, optimization, and simulation.

Such a system provides an improvement over the prior art.

By way of summary, there are two basic parts to the present invention. The first basic part of the present invention enables the same equipment model to be used in both (i) a simulation by a sequential modular computation, and (ii) the simultaneous simulation (or optimization) of the entire plant model. In other words, each equipment model can be executed in two modes as follows.

Mode A:

Given equipment operating parameters and the feed conditions, the equipment (process unit) model solves for the product streams of the corresponding piece of equipment. This means that the equipment model can be executed as a part of the sequential modular computation of the plant model.

Mode B:

An equipment model is able to participate in the simultaneous simulation of the entire plant model by computing items which are needed by the simulator which solves the total plant model.

To that end, each equipment model of the present invention has a dual execution mode capability, as described in detail below.

The second basic part of the present invention is that each equipment model, at the end of the plant simulation or optimization, stores the results to a plant model file, which is used with both modes of the equipment model execution.

This part of the present invention enables the solution of the sequential modular simulation and the solution of the simultaneous simulator/optimizer to be mutually shared. Hence, initial plant simulation is carried out by a sequential modular simulation. The results are stored in the plant model file. The results of the sequential modular simulation are then used as the initial, starting point for the simultaneous simulation and optimization of the plant model.

Results obtained by the simultaneous simulation of the plant model are also stored in the plant model file. Therefore, one can use these results to run a sequential modular plant simulation.

In the present invention, initial simulation of a desired process plant by a sequential modular routine enables the convergence of the plant model (i.e., solution thereof) with a very small number of specifications or initial guesses entered by the plant model developer/engineer. This solution then

serves as the starting point for the optimization of the plant model by the simultaneous simulation routine. Since the simultaneous simulation routine starts from a feasible point (solution by the sequential modular routine), the simultaneous simulator/optimizer converges to an optimum point in a robust manner."

See, also: fig. 1-2; col. 1, line 45 to col. 4, line 33.

24. [Skeirik (*of record*) *or* Atherton (Applicant's IDS) *or* Iwasaki et al. (Applicant's IDS) *or* Litt et al. (Applicant's IDS) *or* Furukawa et al. (*of record*) *or* Carrette et al. (*of record*) *or* Leitch et al. *or* Ketcham et al. *or* Bernstein et al. *or* Ehrlich et al. *or* Arai et al. *or* Britt et al.] do not disclose biopharmaceutical applications and details pertinent to biopharmaceutical applications. Applicant has admitted that (page 23, lines 13-27, specification) that the invention is a general simulation procedure for batch processes *other* than *just* for biopharmaceutical applications. Official Notice is taken that one of ordinary skill in the art at the time of the invention would recognize and choose the appropriate process and quality control variables as necessary for the particular application.

Response to Arguments

25. Applicant's arguments filed 5/23/2000 have been fully considered but they are not persuasive.

26. The examiner notes that the claims are directed to the use of process simulation to determine scheduling. The examiner has obtained hundreds of patents regarding the modeling of

process and quality control, and scheduling. There are also many patents on the use of expert systems as per process control and modeling, including real-time modules as well as simulations.

27. Applicant's argument (last paragraph, page 11, paper # 7) is that the references all deal with real-time process control, and, that in contrast, the invention is directed to scheduling of quality control sampling in order to arrive at an optimal facility design (*which, in fact, has not been claimed*). In other words, representative is arguing that the *inventive step* is that the simulation is carried out *prior* to implementation of a manufacturing process. Representative has not provided specific examples to buttress the assertion that this has not been disclosed in the prior art. See, for example, Atherton (col. 4, lines 43-47). Col. 5, line 65 to col. 6, line 42 discloses:

> "The *present invention provides the generation of factory schedules from the factory-specific models for distributed factories which have fabrication sequences. The schedule lists lot movements and machine loadings. The factory-specific model contains the scheduling rules of the factory and it simulates the detailed behavior in time of the factory. After initialization with the state of the factory, the simulation calculates and lists the lot movement and machine loadings for the indicated planning horizon. Furthermore,* ***the scheduling rules can be evaluated by the model prior to being implemented in the factory***.
>
> *The invention provides for use of the factory-specific model for the automatic control of the factory including feed-back and feed-forward control of lot movements, machine loadings, and processing. The CIM system provides data on the performance of the factory to the schedule generated* above. The factory may deviate from the schedule due to random events like equipment failure or the loss of a lot, or unplanned events like a new product order. The factory-specific model generates control actions for the factory so that the perturbations in desired factory behavior due to unexpected events are minimized.
>
> This invention provides for a computer-integrated *manufacturing production control system which incorporates a factory-specific model for automatic control. The factory-specific model can also to provide sizing data for the design of the computer-integrated manufacturing (CIM) production-control system. The* ***model provides simulated results on material movements, queue sizes, factory transactions, and other information.*** *Such simulated results are necessary to size computers,*

communications networks, data bases and other aspects of the computer system for manufacturing control.

Because the modeling process of this invention starts with a definition of how a manufacturing plant actually operates, rather than a mathematical theory which ultimately leads to a definition of the plant operation, this modeling process is able to handle very complex manufacturing plants and processes, such as those used in the manufacture of integrated circuits. However, *the results obtained with his process should make* ***it of use in a wide variety of other manufacturing plants and processes as well***."

28. There are no limitations disclosing *how the simulation results can be used* or *that they are actually used* for the stated purpose. Applicant is only claiming a simulation of a scheduling process quality control for a specific industry. In any case, the issue of *real-time* is not a relevant issue. Most modern real-time manufacturing process control systems are tied to *real-time* simulation modules (such as those which use Expert Systems - including those disclosed by Skeirik, as provided in the last Official Office Action) so that process-control can be dynamically updated, controlled and *reconfigured.*

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Bourne et al. discloses an intelligent system for geneating and executing a sheet metal bending plan. See: abstract; col. 4, line 46 to col. 12, line 18.

- Hopkins et al. disclose a method of controlling a manufacturing process using multivariate analysis. See: abstract; fig. 3; col. 2.

- Mozumder et al. disclose a multi-variable statistical process controller for discrete manufacturing. See: abstract; fig. 1; col. 1-2.

- Faccenda et al. disclose "*A combined simulation/optimization approach to process plant design.*" See: section 2 (simulation module); section 3.1 (Characteristics of Optimization Problem); section 5.3 (Analysis Process).

- Ward et al. disclose an integrated process control planning system. See: abstract; fig. 1-4, 8; col. 2-3; col. 9-10; col. 14.

- Fisher et al. discloe a process control method for improving manufacturing operations. See: abstract; fig. 1-2; col. 3-4.

- Atsumi discloses an order processing control module. See: abstract; fig. 1-3; col. 1-3.

30. This is a ~~continuation of applicant's earlier Application No. 09,100,088~~ CONTINUED PROSECUTION APPLICATION (CPA). All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

31. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Hugh Jones whose telephone number is (703) 305-0023.

ERIC W. STAMBER
PRIMARY EXAMINER

Dr. Hugh Jones

December 29, 2000